



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/749,640

12/31/2003

Lawrence M. Boyd

1842-0021

9392

7590

10/05/2009

Michael D. Beck
Suite 3000
111 Monument Circle
Indianapolis, IN 46204-5115

EXAMINER

HARVEY, JULIANNA NANCY

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

10/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/749,640	Applicant(s) BOYD ET AL.	
	Examiner Julianna N. Harvey	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37,38,41-47 and 52-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37,38,41-45 and 52-59 is/are rejected.
- 7) ☒ Claim(s) 46 and 47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12 May 2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Nowhere in Applicant's disclosure is there support for allowing substantially full natural rotation of the motion segment in the A/P plane in both directions during normal flexion and extension (claim 54). Para. 0068 of the publication (US 2005/0143823 A1) states that the invention offers a center of rotation that is as close as possible to the normal center of rotation and that the invention allows the disc to experience more normal loading patterns during flexion and extension. Accordingly, claims 54-59 contain new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 3733

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37, 41, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley (US 6,610,091 B1) in view of Goble et al. (US 2002/0072800 A1). Regarding **claim 37**, Reiley discloses a method for dynamic stabilization of motion segments of the spine comprising the steps of: positioning a stabilization element ("500" in Fig. 12) adjacent the spine, the stabilization element configured to span a length of the spine between at least two vertebrae; engaging bone anchors ("330" in Fig. 12) to at least two vertebrae; and coupling the bone anchors to the stabilization element, with at least one of the bone anchors coupled to permit deflection ("315" may be made of rubber; col. 6, lines 7-24) of the bone anchor between the stabilization element and the corresponding vertebra to which the at least one of the bone anchors is engaged (Fig. 12; col. 8, lines 8-26; col. 9, lines 38-45; col. 10, lines 30-41). Regarding **claim 41**, Reiley discloses a method for dynamic stabilization of a motion segment of the spine comprising the steps of: coupling a dynamic stabilization system ("500" in Fig. 12) across the motion segment, the system including at least one bone anchor ("330" in Fig. 12; "520a" in Fig. 11) engaged in each of two vertebrae that permits natural motion of the motion segment by deforming a portion of the bone anchor ("315" may be made of rubber; col. 6, lines 7-24) (Fig. 12; col. 8, lines 8-26; col. 9, lines 38-45; col. 10, lines 30-41). Regarding **claim 52**, Reiley discloses a method for dynamic stabilization of a motion segment of the spine comprising the steps of: positioning a stabilization element ("500" in Fig. 12) configured to span a length of the spine between at least two vertebrae; and engaging a bone anchor ("330" in Fig. 12; "520a" in Fig. 11) in each of

Art Unit: 3733

the at least two vertebrae, each of the bone anchors including a head portion ("320" in Fig. 12; head portion of anchor "520a" unlabeled in Fig. 13) configured for contacting the stabilization element, and an engagement portion (stem unlabeled in Fig. 12 but labeled as "310" in Fig. 4; stem of "520a" unlabeled in Fig. 13) configured for engaging a vertebra, the bone anchor engaged in at least one of the vertebrae including a flexible portion ("315" in Fig. 12) between the head portion and the engagement portion configured to permit movement of the head portion relative to the engagement portion ("315" may be made of rubber; col. 6, lines 7-24) (Fig. 12; col. 8, lines 8-26; col. 9, lines 38-45; col. 10, lines 30-41). Reiley fails to teach repairing or replacing all or part of the intervertebral disc between at least two vertebrae (**claims 37 and 52**) and introducing a device into an intervertebral space to at least partially maintain or restore the natural motion of the disc at the motion segment (**claim 41**). Goble et al. teach that facet joint replacement in conjunction with artificial disc replacement recreates a fully functional motion segment that is compromised due to disease or trauma, and that together, facet joint and disc replacement can eliminate substantially all sources of pain, return full function and range of motion, and restore the natural biomechanics of the spinal column (para. 0011). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Reiley method such that it includes repairing or replacing all or part of the intervertebral disc between at least two vertebrae (**claims 37 and 52**) and introducing a device into an intervertebral space between two vertebrae to at least partially maintain or restore the natural motion of the disc at the motion segment (**claim 41**), as suggested by Goble et al., as doing so can eliminate substantially all

Art Unit: 3733

sources of pain, return full function and range of motion, and restore the natural biomechanics of the spinal column.

Claims 38, 42-44, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley (US 6,610,091 B1) in view of Goble et al. (US 2002/0072800 A1) as applied to claims 37, 41, and 52 above, and further in view of Bao et al. (US 5,534,028 A). Reiley and Goble et al. teach the claimed invention except that the step of repairing or replacing includes replacing all or part of the nucleus pulposus with a polymeric prosthesis having physical properties substantially similar to the physical properties of a natural nucleus pulposus (**claims 38 and 53**), that the device includes a device for replacing or augmenting the nucleus pulposus of the intervertebral disc (**claim 42**), that the step of introducing a device includes introducing a polymeric prosthesis to replace or augment the nucleus pulposus in which the polymeric prosthesis exhibits physical properties similar to the natural nucleus pulposus (**claim 43**), and that the polymeric prosthesis is formed from a hydrogel (**claim 44**). Bao et al. teach a prosthetic nucleus pulposus made of hydrogen, a polymer, that has physical properties that are substantially similar to the physical properties of a natural nucleus pulposus (col. 3, lines 13-24). It would have been obvious to one of ordinary skill in the art to further modify the Reiley method such that the disc replacement is the Bao et al. prosthetic nucleus pulposus (**claims 38, 42-44, and 53**) as such a prosthesis is consistent with Goble et al. and would allow for partial disc replacement as some situations may only require replacement of the nucleus pulposus.

Claims 42 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley (US 6,610,091 B1) in view of Goble et al. (US 2002/0072800 A1) as applied to claim 41 above, and further in view of Fleischmann et al. (US 6,375,682 B1). Reiley and Goble et al. teach the claimed invention except that the device includes a device for replacing or augmenting the nucleus pulposus of the intervertebral disc (**claim 42**) and that the device for replacing or augmenting the nucleus pulposus is a mechanical device (**claim 45**). Fleischmann et al. teach a mechanical device for replacing the nucleus pulposus wherein the device can be adjusted to fit the individual patient and allows for post-operative adjustments (col. 6, lines 43-52; col. 3, lines 19-25). It would have been obvious to one of ordinary skill in the art to further modify the Reiley method such that the disc replacement is the Fleischmann et al. mechanical nucleus pulposus (**claims 38 and 42-44**) as such a prosthesis is consistent with Goble et al. and would allow for post-operative adjustments.

Allowable Subject Matter

Claims 46 and 47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 12 May 2009 have been fully considered but they are not persuasive. With respect to Applicant's argument that the Reiley cup member is not

Art Unit: 3733

deflectable (pages 6-7 and 10), the examiner respectfully points out that the statement by Applicant that "some rubbers are not readily deformed, and it appears that this is the type of rubber contemplated by Reiley" is merely speculation by Applicant. In addition to being made of rubber, Reiley also discloses that the cup member may be made of polyethylene (col. 6, lines 7-16). The cup member provides an articulation surface for the joint and thus must absorb impact between the upper and lower vertebrae of the joint. LDPE is known to be used in orthopedic devices to provide shock absorbance and is also known to be deflectable. Furthermore, dictionary.com defines "rubber" as "a highly elastic solid substance" and "a material made by chemically treating and toughening this substance, valued for its elasticity, nonconduction of electricity, shock absorption, and resistance to moisture, used in the manufacture of erasers, electrical insulation, elastic bands, crepe soles, toys, water hoses, tires, and many other products". Thus, based on the definition of "rubber" and the disclosure of another deflectable material, the Reiley cup member can be deflectable. With respect to Applicant's argument that the Reiley prosthesis is not coupled to the stabilization element (pages 7-8 and 10-11), the examiner respectfully points out that dictionary.com defines "couple" as "to fasten, link, or associate together in a pair or pairs". At the very least, the prosthesis and stabilization element are associated together. With respect to Applicant's argument that claim 41 requires that a bone anchor in each of the two vertebrae deform (pages 8-9), the examiner respectfully points out that this is not required by claim 41. Claim 41 recites "deforming a portion of the bone anchor" where "the bone anchor" indicates a single bone anchor, not both bone anchors. With respect

Art Unit: 3733

to Applicant's argument that the Reiley head portion is not configured for engagement to the stabilization element (page 9), the examiner respectfully points out that dictionary.com defines "engage" as "to attach or secure", "attach" as "to fasten or affix; join; connect", "connect" as "to join, link, or fasten together; unite or bind" and "join" as "to bring in contact, connect, or bring or put together". Thus, the Reiley head portion is configured to engage the stabilization element.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 3733

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julianna N. Harvey whose telephone number is 571-270-3815. The examiner can normally be reached on Mon. - Fri., 8:00 a.m. - 4:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. N. H./

Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733